

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Karen M. Williams,
Magistrate Judge

**THE ZHP PARTIES' SUPPLEMENTAL BRIEF IN SUPPORT OF THEIR
MOTION FOR A PROTECTIVE ORDER PRECLUDING THE
DEPOSITION OF ZHP PRESIDENT BAOHUA CHEN**

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
I. PLAINTIFFS COMPLETED FOUR DEPOSITIONS SINCE THE FILING OF THE ZHP PARTIES’ MOTION FOR PROTECTIVE ORDER.....	2
II. THE RECENT DEPOSITION TESTIMONY FURTHER CONFIRMS THAT MR. CHEN HAD NO MATERIAL INVOLVEMENT IN ANY OF THE KEY FUNCTIONS OF THE ZHP PARTIES AT ISSUE IN THIS LITIGATION.....	3
III. PLAINTIFFS STILL HAVE NOT REBUTTED THE PRESUMPTION AGAINST MR. CHEN’S DEPOSITION UNDER THE APEX DOCTRINE.....	4
A. Mr. Chen Is Not the Only Connection Between ZHP, Shanghai Syncores, Prinbury, Huahai US, Princeton, and Solco	5
B. Mr. Chen Does Not Possess Unique Knowledge as to the FDA.....	6
C. Mr. Chen Does Not Possess Unique or Superior Knowledge as to the Cost of Manufacturing.....	9
D. Mr. Chen Does Not Possess Unique Knowledge as to the Recall of Valsartan	10
E. Mr. Chen Was Not Involved in the Irbesartan Development Process or Plaintiffs’ Fabricated Cover Up.....	11
CONCLUSION.....	13

INTRODUCTION

Since the ZHP Parties filed their Motion for Protective Order precluding the deposition of ZHP President Baohua Chen ([Dkt. 1247](#)), Plaintiffs have taken four more depositions, including the deposition of Jun Du, the Vice Chairman of ZHP's Board of Directors and the chief executive of ZHP's U.S. entities.¹ Plaintiffs have now completed *17 depositions* of ZHP Party witnesses, ten of whom were designated as corporate representatives to testify on the *59 topics* in Plaintiffs' 30(b)(6) notice of deposition. Even with the four additional depositions, Plaintiffs are no closer to rebutting the presumption against Mr. Chen's deposition because their testimony, like that of the other 13 ZHP Party witnesses who have been deposed, confirms that Mr. Chen has no unique information about the material facts at issue.

Accordingly, for the reasons discussed below, and as discussed in the ZHP Parties' opening brief, which is explicitly incorporated herein, the Court should grant the ZHP Parties' Motion for Protective Order and preclude a deposition of Mr. Chen under the apex doctrine.

¹ The Court granted the ZHP Parties leave to file this supplemental brief during the hearing on May 3, 2021, and during the Case Management Conference on June 3, 2021.

I. PLAINTIFFS COMPLETED FOUR DEPOSITIONS SINCE THE FILING OF THE ZHP PARTIES' MOTION FOR PROTECTIVE ORDER

1. ***Jun Du, Vice Chairman of Zhejiang Huahai Pharmaceutical Co., Ltd., and CEO of Huahai U.S., Inc., Princeton Pharmaceuticals Inc., and Solco Healthcare U.S.***

Jun Du is the Vice Chairman of ZHP and CEO of Huahai U.S., Princeton, and Solco. He was deposed on May 27, 2021 and May 28, 2021 in his individual capacity. [Dkt. 1163](#). Notably, a number² of the documents cited by Plaintiffs in their December 21, 2020 letter requesting Mr. Chen's deposition also reference Mr. Du. [Dkt. 685](#).

2. ***Jie (Jay) Wang, Vice President of Business Development at Zhejiang Huahai Pharmaceutical Co., Ltd.***

Jie Wang is the Vice President of Business Development at ZHP and was designated to testify on *eight 30(b)(6) topics*. [Dkt.1227](#). Jie Wang was deposed on May 17, 2021 and May 18, 2021 regarding:

- Communications with API and finished dose customers and downstream customers (Topics 42 and 43);
- Credits, indemnification, refunds, and/or penalties paid or provided by or to ZHP (Topic 47); and
- Product tracing and pricing and sales of valsartan API and valsartan finished dose ultimately sold in the United States (Topics 50, 52, 54, 56, and 58).

² Specifically, eight such documents (Exs. C, E, G, H, K, N, O, and R to Plaintiffs' December 21, 2020 Letter) also reference Mr. Du.

3. ***Xiaodi Guo, Chief Scientific Officer and Executive Vice President at Princeton Pharmaceutical, Inc. and Prinbury Biopharm Co. Ltd.***

Xiaodi Guo is an Executive Vice President and the Chief Scientific Officer at Princeton, in addition to serving as the Chief Scientific Officer for Prinbury Biopharm Co. Ltd. He was deposed on May 19, 2021 and May 20, 2021 in his individual capacity. [Dkt. 1236](#).

4. ***Mi (Karen) Xu, Associate Vice President in Sales Department (European API, Generic Accounts, and Market Development) at Zhejiang Huahai Pharmaceutical Co., Ltd.***

Mi Xu is an Associate Vice President in the Sales Department at ZHP responsible for European API, Generic Accounts, and Market Development. She was also deposed on May 19, 2021 and May 20, 2021 in her individual capacity. [Dkt. 1169](#).

II. THE RECENT DEPOSITION TESTIMONY FURTHER CONFIRMS THAT MR. CHEN HAD NO MATERIAL INVOLVEMENT IN ANY OF THE KEY FUNCTIONS OF THE ZHP PARTIES AT ISSUE IN THIS LITIGATION

At his deposition, Mr. Du confirmed that Mr. Chen, as the highest-ranking executive at ZHP, had no material involvement in the valsartan manufacturing, testing, analytical, quality control, quality assurance, research and development, recall, regulatory and sales functions at issue in this litigation. Instead, Mr. Du explained that substantive decision-making in these key areas was made by the

relevant departments, and not ZHP's board or General Manager. Specifically, Jun Du explained that:

1. Responses to the FDA detailing ZHP's deviation investigations following FDA's inspections were compiled and drafted by ZHP Quality Assurance ("QA"), Quality Control ("QC"), Technology, and Analytical Departments, *see* Ex. A, Jun Du Tr., 5/27/2021 at 57:19-60:5; Ex. B, Jun Du Tr., 5/28/2021 at 270:14-274:5;
2. Investigations regarding unknown peaks was performed by ZHP QC or Technical Departments, *see* Ex. A Jun Du Tr., 5/27/202 at 180:23-184:4;
3. Review, investigation, and responses to an internal July 27, 2017 email regarding irbesartan lab scale processes were handled by ZHP QA, Technology, Manufacturing, and CEMAT Departments, *see id.* at 137:4-139:7; Ex. B, Jun Du Tr., 5/28/2021 at 257:21-268:8;
4. Calculations and determinations regarding profits and sales were made by ZHP Finance and Sales departments; *see* Ex. A, Jun Du Tr., 5/27/2021 at 198:7-199:1.

Plaintiffs have not and cannot point to any evidence contradicting Mr. Du's testimony that decision-making in these areas was directed by anyone other than department heads and their personnel, and there is no basis to believe that Mr. Chen possesses any unique or superior knowledge on these subjects.

III. PLAINTIFFS STILL HAVE NOT REBUTTED THE PRESUMPTION AGAINST MR. CHEN'S DEPOSITION UNDER THE APEX DOCTRINE

Nowhere in ZHP's voluminous discovery, which includes more than 350,000 documents from more than 83 custodians and 17 depositions, is there a document or testimony that even suggests Mr. Chen had any material involvement in any of the

manufacturing processes, regulatory affairs, sales, FDA inspections and communications, customer communications and recall, or quality control and insurance functions at issue. If anything, the record—and the few documents relied upon by Plaintiffs thus far in this litigation—demonstrate that Mr. Chen would only possess duplicative, cumulative information about the highly technical subjects at issue.

A. Mr. Chen Is Not the Only Connection Between ZHP, Shanghai Syncores, Prinbury, Huahai US, Princeton, and Solco

In their December 21, 2021 Letter, Plaintiffs claim, without any support, that Mr. Chen “is the only connection between ZHP, Shanghai Syncores, Prinbury, Huahai US, Princeton, and Solco.” *See* [Dkt. 685](#) at 10. However, the latest testimony offered by Jun Du only compounds the prior testimony already offered by Eric Gu, Eric Tsai, and Hai Wang, demonstrating that this assertion by Plaintiffs is plainly untrue. *See* ZHP Moving Brief at 18-19.

Mr. Du is the current Vice Chairman of the ZHP Board of Directors. *See* Ex. A, Jun Du Tr., 5/27/2021, at 25:24-26:3. Jun Du is also the Chief Executive Officer of Princeton, Huahai US, and Solco, as well as the former CEO of Prinbury Biopharm. *Id.* at 40:13-18; 40:23-41:3; 42:8-10; 54:5-12. Clearly, Mr. Du is a meaningful connection between ZHP, Prinbury, Huahai US, and Solco.

As to Mr. Chen’s roles with these entities, Jun Du testified that Mr. Chen is the former Chair of the ZHP Board of Directors and the current General Manager of

ZHP. *Id.* at 26:4-27:12. In addition, Mr. Du testified that Mr. Chen is *not* an executive at Shanghai Syncores, but instead is that entity's legal representative, or "an agent for the company registration." *Id.* at 28:11-23; 30:11-16. Given that Mr. Du confirmed that Mr. Chen's role at Shanghai Syncores is not one of executive leadership, but rather a legal representative for purposes of company registration, there is no factual basis to believe that Mr. Chen has or could possess any unique knowledge about Shanghai Syncores that would constitute material facts at issue in this litigation.

Plaintiffs were afforded the opportunity to depose Jun Du for *over nine and a half hours*, and there is no reasonable argument to be made that Plaintiffs require additional testimony from Mr. Chen to probe the connections among these entities in order to discover relevant information that could not have already been provided by Jun Du.

B. Mr. Chen Does Not Possess Unique Knowledge as to the FDA

Plaintiffs' claim that Mr. Chen has unique knowledge and played "a central role at ZHP" regarding FDA inspections and communications with the FDA, *see Dkt. 685* at 11, is also belied by the Jun Du's testimony in response to extensive questioning on these topics. Mr. Du testified that he has periodically held the interim title of Executive Vice President of ZHP for the specific purpose of coordinating ZHP's interactions with the FDA regarding audits, inspections, and communications

deriving therefrom when Mr. Chen was unavailable. *See id.* at 33:7-34:24. Mr. Du also confirmed that he held this title during the summer of 2018 when the FDA conducted the audits of ZHP that form the central focus of this litigation. *Id.* at 34:22-35:13. Mr. Du, ***not Mr. Chen***, attended the FDA inspections regarding the nitrosamine impurities at issue.

Plaintiffs had ample opportunity to engage Mr. Du in comprehensive questions about ZHP's interactions with the FDA, including FDA inspections, audits, warning letters, correspondence, ZHP response letters, deviation reports and investigations, and recall-related press releases and statements. By way of example, ***78 pages*** of the 265 pages of testimony from Mr. Du's deposition transcript (approximately 29%) center on the above FDA-related topics. Furthermore, 12 of 23 exhibits³ (excluding translations of documents) that Plaintiffs showed Mr. Du were related to FDA correspondence, inspections, deviation investigations, or recall procedures and statements.

Plaintiffs questioned Mr. Du extensively about the ZHP Parties' interactions with the FDA, including many of this case's key documents on which Jun Du's name

³ It is also worth noting that all but one of these 12 exhibits, an August 26, 2018 Letter in Response to an FDA Inspection signed by Jun Du on behalf of ZHP, were also shown to previous ZHP witnesses at deposition, thereby illustrating the exhaustive opportunities that Plaintiffs have had to obtain testimony about these topics.

appeared or that were signed by him on behalf of ZHP. *See* Ex. B, Jun Du Tr., 5/28/2021 at 230:6-232:7 (testimony regarding FDA Establishment Inspection Report from Jul. 23-Aug. 3, 2018); 227:12-229:50; 232:8-234:6 (testimony regarding Aug. 26, 2018 ZHP Response Letter to FDA); and 234:13-243:21; 247:17-251:15 (testimony regarding Nov. 29, 2018 FDA Response Letter). Although Plaintiffs' questioning of Mr. Du regarding the FDA interactions was comprehensive, if Plaintiffs wanted to ask more questions about FDA inspections, communications, the ZHP Parties' responses thereto, or Mr. Chen's involvement therein, they had the opportunity to ask these questions to Mr. Du over the course of his two-day deposition, which they concluded prior to the expiration of the allotted time.

Plaintiffs have had the opportunity to ask no less than eleven witnesses—Linda Lin, Min Li, Xiaodi Guo, Minli Zhang, Eric Tsai, Jucai Ge, Qiangming Li, Peng Dong, Jie Wang Remonda Gergis, and now, Jun Du, who is specifically appointed to facilitate certain FDA inspections—about FDA inspections and communications. Accordingly, the information sought on these topics could have been—and has been—obtained through lower level employees and does not require the testimony of Mr. Chen.

C. Mr. Chen Does Not Possess Unique or Superior Knowledge as to the Cost of Manufacturing

In support of their claim that “Mr. Chen used his central role at ZHP to exert pressure to develop and cut the cost of the manufacturing process at issue in this case,” Dkt. 685 at 13, Plaintiffs cite to a page within the FDA Establishment Inspection Report from Jul. 23-Aug. 3, 2018 where ZHP communicated with the FDA about its reasoning for changing the manufacturing process. *Id.* The portion of this document that Plaintiffs have cited in support of their alleged need to depose Mr. Chen actually refers to a comment purportedly made by *Jun Du*. *See* Ex. V to ZHP’s Moving Brief. ***Indeed, Mr. Du provided testimony on this topic during his deposition.*** *See* Ex. B, Jun Du Tr., 5/28/2021, at 230:6–232:7. Mr. Du also testified extensively about ZHP’s manufacturing process change, and the manufacturing cost considerations that accompanied it. *See id.* at 232:8-243:21; 247:17-250:22. And, nothing in Mr. Du’s testimony on this topic suggests that Mr. Chen possesses any knowledge of the manufacturing change or its costs, let alone any knowledge that is *unique and superior* to justify an apex deposition.

As with the FDA-related topics, Plaintiffs had ample opportunity to question Mr. Du on Mr. Chen’s role and/or influence related to the manufacturing process change and cost and pricing decisions, however, they chose not to do so. Similarly, but more importantly, Jie Wang was specifically designated to testify as ZHP’s

corporate representative on *several* 30(b)(6) topics covering manufacturing costs⁴, yet Plaintiffs ignored their opportunity to elicit *any* meaningful testimony on this subject from ZHP's corporate designee. Instead, Jie Wang was asked in the broadest terms about benchmark pricing, but with respect to the gross and net profits from sale of API, Plaintiffs did not ask not direct questions about profits. *See* Ex. C, Jie Wang Tr., 5/19/2021 at 229:10-264:10. Insofar as Plaintiffs sought answers to their questions about ZHP's pricing considerations or strategy, they had multiple opportunities to do so from both lower level employees, department heads, and a high-ranking executive.

D. Mr. Chen Does Not Possess Unique Knowledge as to the Recall of Valsartan

As explained in the ZHP Parties' moving brief, Plaintiffs have not and cannot identify any unique knowledge Mr. Chen has regarding the recall of valsartan. *See* ZHP Moving Brief at 26-27. This fact is reinforced by the testimony provided by Jie Wang, Xioadi Guo, Karen Xu, and Jun Du. Plaintiffs had the opportunity to question these four witnesses for a total of over 30 hours (excluding translation time added), and did not uncover any facts to suggest that Mr. Chen was involved in the valsartan recall in any meaningful way. This recent testimony, combined with the prior

⁴ Jie Wang was designated to testify on eight 30(b)(6) topics, including product tracing, pricing and sales of valsartan API, and valsartan finished dose ultimately sold in the United States (Topics 50, 52, 54, 56, and 58).

testimony of Eric Gu and Jucai Ge explaining Mr. Chen's extremely limited role with regard to the valsartan recall further illustrates that Mr. Chen does not possess any unique or superior knowledge that was not already provided by the testimony of Yuelin Hu, Qiangming Li, Jucai Ge, Eric Gu, or Hai Wang, all of whom were either members of the Recall Group (Hu, Li, and Ge), or who already testified about the valsartan recall.

E. Mr. Chen Was Not Involved in the Irbesartan Development Process or Plaintiffs' Fabricated Cover Up

Finally, despite Plaintiffs' insistence to the contrary, Mr. Chen has nothing to do with the July 27, 2017 Jinsheng Lin Email. *See* Ex. M to ZHP's Moving Brief. At his deposition, Plaintiffs subjected Mr. Du to repeated, exhaustive questioning about this email, but in doing so did not uncover a single fact to suggest that Mr. Chen was involved in any way whatsoever in the irbesartan development or any fabricated cover up resulting from Dr. Lin's email. That, of course, is because Mr. Chen had no knowledge of the email and the purported "cover up" is product of Plaintiffs' imagination.

And Plaintiffs have had ample opportunity to take testimony on the Jinsheng Lin Email. Over the course Mr. Du's deposition, Plaintiffs questioned Jun Du about the July 27, 2017 email or its contents for ***approximately 3 hours***, and asked him ***over 100 questions*** about this topic alone. During the afternoon portion of the first day of Jun Du's deposition, Jun Du testified almost exclusively about this email for

nearly 2.5 consecutive hours. *See* Ex. A, Jun Du Tr., 5/27/2021 at 101:8-170:17. During this extensive testimony, Mr. Du consistently indicated that the substantive decision-making regarding ZHP's review, investigation, and response regarding this email was, and will continue to be, made by the relevant departments and department heads within ZHP, all of whom are beneath Jun Du and Mr. Chen. *See, e.g., id.* at 137:4-139:7; Ex. B, Jun Du Tr., 5/28/2021 at 257:21-268:8.

Not only have Plaintiffs asked Mr. Du *more than 100 questions* about this single email, they have also extensively questioned 7 other ZHP Party witnesses about it⁵. Given all of the testimony about this one email, *which still has not been linked to Mr. Chen in any way*, Plaintiffs have no legitimate basis for seeking Mr. Chen's testimony about it.

⁵ In addition to Mr. Du, Linda Lin, Xiaodi Guo, Jucai Ge, Karen Xiu, Jie Wang, Min Li, and Yuelin Hu have all testified about this email.

CONCLUSION

WHEREFORE, for all of the foregoing reasons, and those stated in the opening brief incorporated by reference herein, the ZHP Parties respectfully request that the Court grant its motion for protective order or hold the motion in abeyance until the additional discovery Plaintiffs have requested is completed.

June 3, 2021

Respectfully submitted,

By: /s/ Seth A. Goldberg

DUANE MORRIS LLP
Seth A. Goldberg
30 South 17th Street
Philadelphia, Pennsylvania 19103
Tel.: (215) 979-1000
Fax: (215) 979-1020
SAGoldberg@duanemorris.com

*Attorneys for Zhejiang Huahai
Pharmaceutical Co, Ltd., Huahai
U.S., Inc., Princeton Pharmaceutical
Inc., and Solco Healthcare US, LLC*